

**What is claimed is:**

1. A method of detecting abnormal cell growth in a mammal, comprising assessing the level of Pin1 in a test sample from the mammal, wherein an elevation in the levels of Pin1 is indicative of abnormal cell growth.
2. The method of claim 1, wherein the level of Pin1 is a protein level.
3. The method of claim 1, wherein the level of Pin1 is a nucleic acid level.
4. The method of claim 1, wherein the test sample is a tissue sample.
5. The method of claim 4, wherein said tissue sample is selected from the group consisting of rectum, the brain, the mouth, central nervous system, breast tissue, the uterine cervix, the endometrium, the head/neck, the skin, parotid tissue, the prostate, the brain, the gall bladder, the esophagus, the colon, the lung, thyroid tissue, parathyroid tissue, the uterus, ovarian tissue, adrenal tissue, and testicular tissue.
6. The method of claim 1, wherein the test sample is a body fluid test sample selected from the group consisting of blood, ascites, serum, semen, prostate fluid, seminal fluid, urine, saliva, sputum, phlegm, pus, mucus, bone marrow, lymph, tears or brain body fluid test sample.
7. The method of claim 1 wherein, detecting the abnormal cell growth in a mammal, comprises the steps of:  
 detecting a level of Pin1 in a test sample; and  
 comparing the level of Pin1 in the test sample with a control level, and wherein a difference in the level of Pin1 in the test sample is indicative of abnormal cell growth in the mammal.

8. The method of claim 1, wherein the abnormal cell growth is cancer.
9. The method of claim 8, wherein the cancer is selected from the group consisting of oligodendroglioma, astrocytoma, glioblastomamultiforme, cervical carcinoma, endometriod carcinoma, endometrium serous carcenoma, ovary endometroid cancer, ovary Brenner tumor, ovary mucinous cancer, ovary serous cancer, uterus carcinosarcoma, breast lobular cancer, breast ductal cancer, breast medullary cancer, breast mucinous cancer, breast tubular cancer, thyroid adenocarcinoma, thyroid follicular cancer, thyroid medullary cancer, thyroid papillary carcinoma, parathyroid adenocarcinoma, adrenal gland adenoma, adrenal gland cancer, pheochromocytoma, colon adenoma mild displasia, colon adenoma moderate displasia, colon adenoma severe displasia, colon adenocarcinoma, esophagus adenocarcinoma, hepatocellular carcinoma, mouth cancer, gall bladder adenocarcinoma, pancreatic adenocarcinoma, small intestine adenocarcinoma, stomach diffuse adenocarcinoma, prostate (hormone-refract), prostate (untreated), kideny chromophobic carcinoma, kidney clear cell carcinoma, kidney oncocytoma, kideny papillary carcinoma, testis non-seminomatous cancer, testis seminoma, urinary bladder transitional carcinoma, lung adenocarcinoma, lung large cell cancer, lung small cell cancer, lung squamous cell carcinoma, Hodgkin lymphoma, MALT lymphoma, non-hodgkins lymphoma (NHL) diffuse large B, NHL, thymoma, skin malignant melanoma, skin basolioma, skin squamous cell cancer, skin merkel zell cancer, skin benign nevus, lipoma, and liposarcoma.
10. A method of claim 2 wherein, the method of detecting the level of Pin1 protein in a test sample from a mammal, comprises the steps of:
  - contacting the test sample with an antibody having specificity for Pin1 under conditions suitable for binding of the antibody to Pin1 thereby resulting in the formation of a complex between the antibody and Pin1;
  - detecting the complex between the antibody and Pin1; and
  - comparing the amount of the complex in the test sample with an amount of a complex in a control sample, wherein an elevation in the amount of the complex between the antibody and Pin1 in the test sample compared to the complex in the control sample is indicative of abnormal cell growth.
11. The method of claim 10, wherein the antibody is a polyclonal antibody.

12. The method of claim 10, wherein the antibody is a monoclonal antibody.
13. The method of claim 10, wherein the antibody is detectably labeled.
14. The method of claim 13, wherein the detectable label is selected from the group consisting of a radioactive, enzymatic, biotinylated and fluorescent label.
15. The method of claim 10, wherein the complex is detected by incubating the complex with a second antibody specific for the complex, wherein the secondary antibody comprises a detectable label.
16. The method of claim 3, wherein the method further comprises the step of performing a polymerase chain reaction with oligonucleotide primers capable of amplifying the Pin1 nucleic acid prior to detection.
17. The method of claim 3, wherein the method further comprises the steps of:  
contacting a test sample obtained from the mammal with a nucleic acid probe to a Pin1 nucleic acid;  
maintaining the test sample and the nucleic acid probe under conditions suitable for a hybridization;  
detecting the hybridization between the test sample and the nucleic acid probe;  
and  
comparing the hybridization in the test sample from the mammal to a control test sample without the cellular proliferation, wherein an elevation in the hybridization signal in the test sample from the mammal compared to the control sample is indicative of abnormal cell growth.
18. A method of determining the stage of cancer in a test sample from a mammal, comprising assessing a level of Pin1 in the test sample, wherein the level of Pin1 correlates with the stage of the cancer.
19. The method of claim 18, wherein the level of Pin1 is a protein level.

20. The method of claim 18, wherein the level of Pin1 is a nucleic acid level.
21. The method of claim 18 wherein, detecting the abnormal cell growth in a mammal, comprises the steps of:  
detecting a level of Pin1 in a test sample; and  
comparing the level of Pin1 in the test sample with a control level, and wherein a difference in the level of Pin1 in the test sample is indicative of abnormal cell growth in the mammal.
22. A method of claim 18 wherein, the method of detecting the level of Pin1 protein in a test sample from a mammal, comprises the steps of:  
contacting the test sample with an antibody having specificity for Pin1 under conditions suitable for binding of the antibody to Pin1 thereby resulting in the formation of a complex between the antibody and Pin1;  
detecting the complex between the antibody and Pin1; and  
comparing the amount of the complex in the test sample with an amount of a complex in a control sample, wherein an elevation in the amount of the complex between the antibody and Pin1 in the test sample compared to the complex in the control sample is indicative of abnormal cell growth.
23. The method of claim 22, wherein the antibody is a polyclonal antibody.
24. The method of claim 22, wherein the antibody is a monoclonal antibody.
25. The method of claim 22, wherein the antibody is detectably labeled.
26. The method of claim 18, wherein the method further comprises the step of performing a polymerase chain reaction with oligonucleotide primers capable of amplifying the Pin1 nucleic acid prior to detection.
27. The method of claim 18, wherein the method further comprises the steps of:

contacting a test sample obtained from the mammal with a nucleic acid probe to a Pin1 nucleic acid;

maintaining the test sample and the nucleic acid probe under conditions suitable for a hybridization;

detecting the hybridization between the test sample and the nucleic acid probe; and

comparing the hybridization in the test sample from the mammal to a control test sample without the cellular proliferation, wherein an elevation in the hybridization signal in the test sample from the mammal compared to the control sample is indicative of abnormal cell growth.

28. The method of claim 18, wherein the cancer is selected from the group consisting of oligodendroglioma, astrocytoma, glioblastomamultiforme, cervical carcinoma, endometriod carcinoma, endometrium serous carcenoma, ovary endometroid cancer, ovary Brenner tumor, ovary mucinous cancer, ovary serous cancer, uterus carcinosarcoma, breast lobular cancer, breast ductal cancer, breast medullary cancer, breast mucinous cancer, breast tubular cancer, thyroid adenocarcinoma, thyroid follicular cancer, thyroid medullary cancer, thyroid papillary carcinoma, parathyroid adenocarcinoma, adrenal gland adenoma, adrenal gland cancer, pheochromocytoma, colon adenoma mild displasia, colon adenoma moderate displasia, colon adenoma severe displasia, colon adenocarcinoma, esophagus adenocarcinoma, hepatocellular carcinoma, mouth cancer, gall bladder adenocarcinoma, pancreatic adenocarcinoma, small intestine adenocarcinoma, stomach diffuse adenocarcinoma, prostate (hormone-refract), prostate (untreated), kideny chromophobic carcinoma, kidney clear cell carcinoma, kidney oncocytoma, kideny papillary carcinoma, testis non-seminomatous cancer, testis seminoma, urinary bladder transitional carcinoma, lung adenocarcinoma, lung large cell cancer, lung small cell cancer, lung squamous cell carcinoma, Hodgkin lymphoma, MALT lymphoma, non-hodgkins lymphoma (NHL) diffuse large B, NHL, thymoma, skin malignant melanoma, skin basolioma, skin squamous cell cancer, skin merkel zell cancer, skin benign nevus, lipoma, and liposarcoma.

29. A method of claim 18 wherein the stage of cancer is determined by assessing a level of a Pin1 nucleic acid in a test sample, comprising the steps of:

performing a polymerase chain reaction with oligonucleotide primers capable of amplifying the Pin1 nucleic acid;

detecting a level of amplified nucleic acid fragments of the Pin1 nucleic acid; and  
comparing the level of amplified nucleic acid fragments in the test sample to a  
sample comprising varying stages of the abnormal cell growth, wherein the stage  
of abnormal cell growth in the mammal is determined.

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30. A method of claim 18 wherein the stage of cancer is determined by assessing a  
level of a Pin1 nucleic acid in a test sample, comprising the steps of:
- contacting a test sample obtained from the mammal with a nucleic acid probe to a  
Pin1 nucleic acid;
- maintaining the test sample and the nucleic acid probe under conditions suitable  
for hybridization of the probe to Pin1 nucleic in the sample;
- detecting the hybridization between the Pin1 nucleic acid of the test sample and  
the nucleic acid probe; and
- comparing the hybridization in the test sample from the mammal to hybridization  
of the nucleic probe to Pin1 in a control, wherein the control sample comprises  
varying stages of the abnormal cell growth, thereby determining the stage of the  
abnormal cell growth in the mammal.

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31. A method of evaluating the efficacy of a treatment of abnormal cell growth in a  
mammal, comprising comparing a level of Pin1 in at least two test samples,  
wherein the test samples comprise a first test sample obtained at a first time and a  
second test sample obtained at a later second time, wherein a decrease in the level  
of Pin1 between the two test samples indicates the efficacy of the treatment of the  
abnormal cell growth in the mammal.

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32. The method of claim 31, wherein the level of Pin1 is a protein level.

33. The method of claim 31, wherein the level of Pin1 is a nucleic acid level.

- 30 34. The method of claim 31 wherein, detecting the abnormal cell growth in a  
mammal, comprises the steps of:
- detecting a level of Pin1 in a test sample; and

comparing the level of Pin1 in the test sample with a control level, and wherein a difference in the level of Pin1 in the test sample is indicative of abnormal cell growth in the mammal.

- 5 35. A method of claim 31 wherein, the method of detecting the level of Pin1 protein in a test sample from a mammal, comprises the steps of:  
  
contacting the test sample with an antibody having specificity for Pin1 under conditions suitable for binding of the antibody to Pin1 thereby resulting in the formation of a complex between the antibody and Pin1;  
  
10 detecting the complex between the antibody and Pin1; and  
  
comparing the amount of the complex in the test sample with an amount of a complex in a control sample, wherein an elevation in the amount of the complex between the antibody and Pin1 in the test sample compared to the complex in the control sample is indicative of abnormal cell growth.
36. The method of claim 31, wherein the antibody is a polyclonal antibody.
37. The method of claim 31, wherein the antibody is a monoclonal antibody.
- 20 38. The method of claim 31, wherein the antibody is detectably labeled.
39. The method of claim 31, wherein the method further comprises the step of performing a polymerase chain reaction with oligonucleotide primers capable of amplifying the Pin1 nucleic acid prior to detection.
- 25 40. The method of claim 31, wherein the method further comprises the steps of:  
  
contacting a test sample obtained from the mammal with a nucleic acid probe to a Pin1 nucleic acid;  
  
maintaining the test sample and the nucleic acid probe under conditions suitable  
30 for a hybridization;  
  
detecting the hybridization between the test sample and the nucleic acid probe;  
  
and

comparing the hybridization in the test sample from the mammal to a control test sample without the cellular proliferation, wherein an elevation in the hybridization signal in the test sample from the mammal compared to the control sample is indicative of abnormal cell growth.

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41. A kit for determining the level of Pin1 in a test sample from a mammal comprising one or more reagents for detecting Pin1.

42. The Kit of claim 41, wherein one of the reagents is an antibody.

43. The kit of claim 41, wherein one of the reagents is a DNA probe.

44. The kit of claim 41, wherein one of the reagents is a control.

45. A method for determining whether a subject having cancer is likely to respond to treatment comprising a Pin1 inhibitor compound, the method comprising:  
assessing the level of Pin1 in a test sample from the subject; and  
comparing the level of Pin1 in the test sample to the level of Pin1 in normal tissue, whereby an increased level of Pin1 in the test sample is indicative that the subject is likely to respond to treatment comprising a Pin1 inhibitor compound.

46. The method of claim 45 wherein the cancer is selected from the group consisting of oligodendroglioma, astrocytoma, glioblastomamultiforme, cervical carcinoma, endometriod carcinoma, endometrium serous carcenoma, ovary endometroid cancer, ovary Brenner tumor, ovary mucinous cancer, ovary serous cancer, uterus carcinosarcoma, breast lobular cancer, breast ductal cancer, breast medullary cancer, breast mucinous cancer, breast tubular cancer, thyroid adenocarcinoma, thyroid follicular cancer, thyroid medullary cancer, thyroid papillary carcinoma, parathyroid adenocarcinoma, adrenal gland adenoma, adrenal gland cancer, pheochromocytoma, colon adenoma mild displasia, colon adenoma moderate displasia, colon adenoma severe displasia, colon adenocarcinoma, esophagus adenocarcinoma, hepatocellular carcinoma, mouth cancer, gall bladder adenocarcinoma, pancreatic adenocarcinoma, small intestine adenocarcinoma, stomach diffuse adenocarcinoma, prostate (hormone-refract), prostate (untreated),



kideny chromophobic carcinoma, kidney clear cell carcinoma, kidney oncocytoma, kideny papillary carcinoma, testis non-seminomatous cancer, testis seminoma, urinary bladder transitional carcinoma, lung adenocarcinoma, lung large cell cancer, lung small cell cancer, lung squamous cell carcinoma, Hodgkin lymphoma, MALT lymphoma, non-hodgkins lymphoma (NHL) diffuse large B, NHL, thymoma, skin malignant melanoma, skin basolioma, skin squamous cell cancer, skin merkel zell cancer, skin benign nevus, lipoma, and liposarcoma.

47. A method of treating an individual suffering from cancer comprising, administering to said individaul a Pin1 inhibitor such that treatment occurs.

48. The method of claim 47 wherein said cancer is selected from the group consisting of oligodendroglioma, astrocytoma, glioblastomamultiforme, cervical carcinoma, endometriod carcinoma, endometrium serous carcenoma, ovary endometroid cancer, ovary Brenner tumor, ovary mucinous cancer, ovary serous cancer, uterus carcinosarcoma, breast lobular cancer, breast ductal cancer, breast medullary cancer, breast mucinous cancer, breast tubular cancer, thyroid adenocarcinoma, thyroid follicular cancer, thyroid medullary cancer, thyroid papillary carcinoma, parathyroid adenocarcinoma, adrenal gland adenoma, adrenal gland cancer, pheochromocytoma, colon adenoma mild displasia, colon adenoma moderate displasia, colon adenoma severe displasia, colon adenocarcinoma, esophagus adenocarcinoma, hepatocelluar carcinoma, mouth cancer, gall bladder adenocarcinoma, pancreatic adenocarcinoma, small intestine adenocarcinoma, stomach diffuse adenocarcinoma, prostate (hormone-refract), prostate (untreated), kideny chromophobic carcinoma, kidney clear cell carcinoma, kidney oncocytoma, kideny papillary carcinoma, testis non-seminomatous cancer, testis seminoma, urinary bladder transitional carcinoma, lung adenocarcinoma, lung large cell cancer, lung small cell cancer, lung squamous cell carcinoma, Hodgkin lymphoma, MALT lymphoma, non-hodgkins lymphoma (NHL) diffuse large B, NHL, thymoma, skin malignant melanoma, skin basolioma, skin squamous cell cancer, skin merkel zell cancer, skin benign nevus, lipoma, and liposarcoma.